UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,467	03/26/2001	Laurent Coen	3495.0174-01	7062

22852 7590 08/28/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,467	COEN ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6-28-06 and 7-14-06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18,21-23 and 34-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,21-23 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7-14-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 6-28-06 has been entered. Claims 17, 18 and 22 have been amended. Claims 36 and 37 have been added. Claims 17, 18, 21-23 and 34-37 are pending and under consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 17 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fairweather et al., 1995 (US Patent 5,443,966) and is repeated for the reasons set forth in the preceding Official action mailed 12-29-05. Applicant's arguments filed 6-28-06 have been fully considered but they are not persuasive.

Applicants amended claim 17 to read on a hybrid fragment of tetanus toxin comprising a fragment C and a fraction of fragment B having 11 amino acid residues (854-1315 of the tetanus toxin holotoxin), and argue that Fairweather does not teach a polypeptide of amino acids 854-1315 of the tetanus toxin holotoxin (amendment, p. 5). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 12-29-05. Since the term "comprising" is open language, therefore, the claim still reads on any hybrid fragment of tetanus toxin having fragment C and 11 amino acid residues of fragment B or more amino acid residues, including the full-length tetanus toxin protein. Fairweather teaches construction of expression plasmid pTet18 expressing a polypeptide which comprises 121 residues of B fragment and all

451 carboxy-terminal residues of C fragment of tetanus toxin. The expressed fusion protein would comprise a fragment C and a fraction of fragment B having 11 amino acid residues (854-1315 of the tetanus toxin holotoxin). Thus, the claims remain rejected under 35 U.S.C. 102(b).

3. Claims 17 and 21 remain rejected under 35 U.S.C. 102(a) as being anticipated by Fishman et al., 1996 (Society for Neuroscience Abstracts, Vol. 22, No. 1-3, pp. 1705) and is repeated for the reasons set forth in the preceding Official action mailed 12-29-05. Applicant's arguments filed 6-28-06 have been fully considered but they are not persuasive.

Applicants amended claim 17 to read on a hybrid fragment of tetanus toxin comprising a fragment C and a fraction of fragment B having 11 amino acid residues (854-1315 of the tetanus toxin holotoxin), and argue that Fishman does not teach a polypeptide of amino acids 854-1315 of the tetanus toxin holotoxin (amendment, p. 5). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 12-29-05. Since the term "comprising" is open language, therefore, the claim still reads on any hybrid fragment of tetanus toxin having fragment C and 11 amino acid residues of fragment B or more amino acid residues, including the full-length tetanus toxin protein. Fishman compares full-length tetanus toxin (TTX) and CF in its capacity to bind and be internalized by neurons by ELISA and shows that TTX is superior to its ganglioside binding fragment CF in the capacity for neuronal binding and internalization. The full-length tetanus toxin protein would comprise a fragment C and a fraction of fragment B having 11 amino acid residues (854-1315 of the tetanus toxin holotoxin). Thus, the claims remain rejected under 35 U.S.C. 102(a).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 17, 18, 21, 23, 34 and 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al., 1996 (Society for Neuroscience Abstracts, Vol. 22, No. 1-3, pp. 1705) in view of Mueller, 1994 (Report, ARO-27890.1-LS, Order No. AD-A290 501, NTIS, p. 1-15) and Hohne-Zell et al., 1993 (FEBS Letters, Vol. 336, No. 1, p. 175-180) and is repeated for the reasons set forth in the preceding Official action mailed 12-29-05. Applicant's arguments filed 6-28-06 have been fully considered but they are not persuasive.

Applicants argue that Fishman, Mueller, nor Hohne-Zell teach or suggest a hybrid fragment of tetanus toxin comprising a fragment C and a fraction of fragment B having 11 amino acid residues (amino acids 854-1315 of the tetanus toxin holotoxin) and one of skill in the art would not be motivated to combine the cited references to develop the claimed invention

(amendment, p. 6). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 12-29-05 and the reasons set forth above under 35 U.S.C. 102(a) rejection. Fishman still reads on the amended claim 17 and one of ordinary skill in the art would be motivated to combine the teachings of Fishman, Mueller and Hohne-Zell to practice the claimed invention with reasonable expectation of success as discussed in the preceding Official action mailed 12-29-05.

7. Claims 17, 21 and 22 remain rejected and newly added claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman et al., 1996 (Society for Neuroscience Abstracts, Vol. 22, No. 1-3, pp. 1705) in view of Khan et al., 1995 (WO 95/04151) and Mueller, 1994 (Report, ARO-27890.1-LS, Order No. AD-A290 501, NTIS, p. 1-15) and is repeated for the reasons set forth in the preceding Official action mailed 12-29-05. Applicant's arguments filed 6-28-06 have been fully considered but they are not persuasive.

Applicants argue that Fishman, Mueller, nor Khan teach or suggest a hybrid fragment of tetanus toxin comprising a fragment C and a fraction of fragment B having 11 amino acid residues (amino acids 854-1315 of the tetanus toxin holotoxin) and one of skill in the art would not be motivated to combine the cited references to develop the claimed invention (amendment, p. 6-7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 12-29-05 and the reasons set forth above under 35 U.S.C. 102(a) rejection. Fishman still reads on the amended claim 17 and one of ordinary skill in the art would be motivated to combine the teachings of Fishman, Mueller and Khan to practice the claimed

invention with reasonable expectation of success as discussed in the preceding Official action mailed 12-29-05.

Information Disclosure Statement

8. The information disclosure statement (IDS) submitted on 7-14-06 was filed and is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Conclusion

No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER